



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369] (formerly Docket No. 2007D-0168)

Draft Guidance for Industry on Bioequivalence Recommendations for Pentosan Polysulfate

Sodium Capsule; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioequivalence Recommendations for Pentosan Polysulfate Sodium." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for pentosan polysulfate sodium capsule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311; FDA-2007-D-0433), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to

consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for pentosan polysulfate sodium capsule.

New drug application 020193 for Elmiron (pentosan polysulfate sodium) capsule was initially approved by FDA in September 1996. There are no approved ANDAs for this product. FDA is now issuing a draft guidance for industry on BE recommendations for generic pentosan polysulfate sodium capsule (Draft Pentosan Polysulfate Sodium Capsule BE Recommendations).

In March 2012, Janssen Pharmaceuticals, Inc. (Janssen), manufacturer of the reference listed drug (RLD), Elmiron, submitted (through its attorneys) a citizen petition requesting that FDA require that any ANDA referencing Elmiron meet certain conditions, including conditions related to demonstrating BE (Docket No. FDA-2012-P-0295). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Draft Pentosan Polysulfate Sodium Capsule BE Recommendations before responding to Janssen's citizen petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for pentosan polysulfate sodium capsule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify

comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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